

REASONS FOR ALLOWANCE

The proposed amendments AFTER FINAL, filed 22 Dec 2009, will be entered because they are deemed to place the application in condition for allowance.

This Office Action is responsive to Applicant's Amendment and Response, filed 22 Dec 2009, in which claims 7, 26-29 and 32 are amended to change the scope and breadth of the claim and new claims 33-49 are added, and the specification is amended to revise the claim of priority.

This application is a domestic application, filed 29 Dec 2003; and claims benefit of US Provisional Application 60/459,501, filed 1 Apr 2003; US Provisional Application 60/456,608, filed 21 Mar 2003; US Provisional Application 60/457,027, filed 18 Mar 2003; US Provisional Application 60/441,335, filed 21 Jan 2003; and US Provisional Application 60/437,516, filed 30 Dec 2002.

Claims 7, 26-29 and 32-49 are pending in the current application and allowed herein.

The following is an examiner's statement of reasons for allowance:

Rejections Withdrawn

Applicant's Amendment AFTER FINAL, filed 22 Dec 2009, with respect to claims 7, 26-29 and 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite

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has been fully considered and is persuasive, as amended claims 7, 26-29 and 32 recite definite the stoichiometric ratios of said solvate.

This rejection has been **withdrawn**.

Applicant's Amendment AFTER FINAL, filed 22 Dec 2009, with respect to claims 7, 26-29 and 32 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claims 7, 26-29 and 32 recite definite the stoichiometric ratios of said solvate.

This rejection has been **withdrawn**.

The closest prior art is Talley et al. (U.S. Patent No. 5,760,068; of record) in view of Rubino et al. (Int. J. Pharm. 65, 1990, 141-145; provided by Applicant in IDS mailed 02 Aug 2004).

Talley et al. discloses the benzene sulfonamide celecoxib.

Rubino et al. teaches crystallization of sulfonamides in the presence of propylene glycol.

The instant invention would not have been obvious over Talley et al. in view of Rubino et al. One of ordinary skill in the art would not have a reasonably expectation of success to combine Talley et al. in view of Rubino et al. because Rubino et al. teaches the formation of a sulfonamide hydrate from crystallization in the presence of propylene glycol and because Brittain (Polymorphism in Pharmaceutical Solids, 1999, p183, 202-208, 219, of record) and Davidovich et al. (American Pharmaceutical Review, 2004, 7(1)

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p10, 12, 14,16, 100, of record) suggest that crystallization is highly unpredictable, requiring an empirical approach, and the highly dynamic nature of crystallization can lead to variations in crystal formation, with minor variations resulting in significant modifications of crystal form. Therefore the instant invention is not suggested or fairly taught by the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 7, 26-29 and 32-49 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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